HHS Public Access

Author manuscript

Am J Infect Control. Author manuscript; available in PMC 2015 October 01.

Published in final edited form as:

Am J Infect Control. 2014 October ; 42(10): 1097–1100. doi:10.1016/j.ajic.2014.06.025.

N95 respirator use during advanced pregnancy

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Abstract

Background—To determine the physiological and subjective effects of wearing an N95 filtering facepiece respirator (N95 FFR) in advanced stages of pregnancy.

Methods—Healthy pregnant women (n = 22) and nonpregnant women (n = 22) had physiological and subjective measurements taken with and without wearing an N95 FFR during exercise and postural sedentary activities over a 1-hour period.

Results—There were no differences between the pregnant and nonpregnant women with respect to heart rate, respiratory rate, oxygen saturation, transcutaneous carbon dioxide level, chest wall temperature, aural temperature, and subjective perceptions of exertion and thermal comfort. No significant effect on fetal heart rate was noted.

Conclusions—Healthy pregnant women wearing an N95 FFR for 1 hour during exercise and sedentary activities did not exhibit any significant differences in measured physiological and subjective responses compared with nonpregnant women.

Keywords

Pregnancy; Respiratory protective equipment; Physiological response; Subjective response; Fetal heart rate

Approximately 60% of US women are employed, accounting for 46% of the national workforce.[1,2] The number wearing a respiratory protective device (RPD), such as a respirator or facemask, is not precisely known, but 3.3 million industrial workers[3] have the use of RPD as a work requirement, and 4.3 million individuals employed as nurses and nursing assistants (92% women)[4] wear RPDs to varying degrees. With the US rate of pregnancy (in women age 15-44 years)[5] at 103/1,000, significant numbers of pregnant working women may be using an RPD. Furthermore, pregnant women are at increased risk for morbidity and mortality from some viral respiratory infectious diseases (eg, SARS, pandemic influenza) that may necessitate the use of an RPD.[6-9]

The respiratory system undergoes pregnancy-associated changes[6,10,11] that might be negatively impacted by an RPD. The N95 class of filtering facepiece respirator (N95 FFR) is

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Conflict of interest: None to report.

the most commonly used RPD in both industrial and health care settings in the United States,[3,12] but little scientific data exist on the physiological and subjective burdens imposed by RPDs on pregnant women,[13-15] and none directly addresses N95 FFRs. The present study was undertaken by the US National Institute for Occupational Safety and Health to evaluate the physiological and subjective effects of wearing an N95 FFR during advanced pregnancy.

MATERIALS AND METHODS

Subject demographics

Twenty-two healthy, nonsmoking women in the second to mid-third trimester of pregnancy (ie, 13-35 weeks gestation) and 22 healthy, nonsmoking, nonpregnant women controls were enrolled in the study. All subjects were experienced RPD users. Mean (SD) demographic values of the pregnant subjects were as follows: gestation, 20.6 (4.5) weeks; age, 28.0 (2.9) years; height, 166.7 (5.7) cm; weight, 73.8 (18.5) kg; and body mass index (BMI), 26.8 (6.0) kg/m^2. Mean (SD) demographic values for the controls were age 26.1 (4.0) years, height 167.5 (5.9) cm, weight 67.5 (9.5) kg, and BMI 24.1 (3.2) kg/m^2. The study was approved by the National Institute for Occupational Safety and Health's Human Subjects Review Board. All subjects provided oral and written informed consent.

Assessment of respirator fit: N95 respirator fit testing

Subjects underwent an Occupational Safety and Health Administration respirator quantitative fit test[16] with either a flat-fold N95 FFR or a premolded, cup-shaped N95 FFR. A subject who did not pass fit testing with the randomized N95 FFR was subsequently fit-tested with the other style, and all subjects ultimately passed fit testing on 1 of the 2 respirator models.

Subject instrumentation

Respiratory rate (RR) and chest wall skin temperature (T_{chest}) were monitored continuously with the Zephyr Bioharness (Zephyr Technology Corp, Annapolis, MD). Heart rate (HR), transcutaneous partial pressure of carbon dioxide ($PtcCO_2$), and pulse-derived oxygen saturation (SpO_2) were monitored continuously with the Tosca 500, a heated (42°C) combination pulse oximeter and CO_2 sensor (Radiometer, Copenhagen, Denmark) attached to the right earlobe. Aural temperature (T_{aural}) was obtained from the left ear with a WelchAllyn Pro 400 tympanic thermometer (Braun, Kronberg, Germany). Fetal heart rate (FHR) was measured with a Bidop ES-100V3 ultrasound fetal Doppler (Koven Technology, St Louis, MO).

Study protocol

Subjects were instrumented, and the order of the trials (N95 FFR) and controls (no N95 FFR) was randomized. For trials, at baseline $PtcCO_2$, subjects donned the N95 FFR (following the manufacturer's instructions) and performed a user seal check.[17] The subjects then performed 3 contiguous 20-minute activity phases consisting of (1) standing upright, (2) exercising by pedaling a Kettler RX7 reclining bicycle ergometer (Ense-Parsit, North Rhine-Westphalia, Germany) at 60 pedal cycles/minute and 50 W resistance, and (3) sitting upright in a chair. T_{aural} was obtained at the beginning of each activity phase and every 5

minutes until phase completion. Subjective impressions of thermal comfort and exertion were obtained simultaneously using the Frank Scale of Perceived (Thermal) Comfort (FSPC),[18] which ranges from a rating of 0 ("the coldest you have ever been") to 10 ("the hottest you have ever been"), and the Borg Rating of Perceived Exertion (BRPE),[19] which ranges from a rating of 6 ("very, very light") to 20 ("very, very hard").

In 17 pregnant subjects, FHR was measured at the beginning and end of each seated and standing session (FHR was not assessed during exercise bicycle ergometer testing owing to motion artifactm[20] and could not be evaluated in 5 subjects during standing and sitting.) There was a minimum 30-minute respite between controls and trials.

Statistical analysis

Physiological and subjective data were summarized at the first (1 minute) and last (20 minutes) time points of each activity phase for statistical analysis. Repeated-measures ANOVA in a mixed design (2 within-subjects factors [condition × time] and 1 between-subjects factor [pregnancy]) was used to determine the main effect of wearing an N95 FFR (condition) on the study variables (except FHR) over different phases (time), along with the effect of pregnancy on each main effect. A Greenhouse-Geisser correction was adopted for assumption of sphericity, and a post-hoc pairwise comparison with Bonferroni adjustment was carried out for a significant F value. A P value < .05 was considered to indicate statistical significance. All analyses were performed using a SPSS version 18 (IBM, Armonk, NY).

RESULTS

Age was the sole demographic that was significantly greater for pregnant subjects (P = .03). Wearing an N95 FFR did not significantly affect any of the physiological or subjective responses in pregnant and nonpregnant subjects: HR (F = 0.582; P = .45), RR (F = 0.042; P = .83), SpO_2 (F = 1.767; P = .19), $PtcCO_2$ (F = 0.971; P = .33), T_{chest} (F = 0.006; P = .93), T_{aural} (F = 1.444; P = .23), BRPE (F = 0.019; P = .89), or FSPC (F = 2.389; P = .13). Wearing an N95 FFR did not significantly affect FHR (F = 0.009; P = .92).

For all subjects, wearing an N95 FFR was associated with a significant effect on RR (F = 12.548; P = .001), and FSPC (F = 34.276; P < .001). Time had a significant effect (P < .05) on all measured variables except $PtcCO_2$ and T_{aural} (Tables 1-3). N95 FFR use was associated with increased $PtcCO_2$ over time during exercise (P = .04).

DISCUSSION

Our study data indicate that the physiological and subjective effects of wearing an N95 FFR during 1 hour of combined sedentary activities and exercise do not differ significantly between healthy pregnant and nonpregnant women.

HR

The effects of N95 FFR use on the normally higher HR of pregnancy (owing to metabolic demands[10]) was not significantly different from those in the nonpregnant subjects in the present series and in other investigations with similar workloads.[21,22]

RR

RR is relatively stable during pregnancy,[10] and no significant differences were noted between pregnant and nonpregnant subjects. The significant (P = .001) overall decreased RR noted with N95 FFR use (Table 1), reflects minor RR decrements (mean, 0.94 breaths/minute; range, 0.1-2.2 breaths/minute, median, 0.9 breaths/minute) reported previously[23] and related to a mild concomitant compensatory increase in the tidal volume.

SpO_2

No significant differences in SpO_2 were noted between pregnant and nonpregnant subjects (Table 1), and no subject had a SpO_2 <97%. A previous study found that in pregnant women in the third trimester, SpO_2 levels did not decrease over normal baseline values after 30 minutes of wearing a gas mask with significantly greater resistance (20 cm H_2O pressure) than an N95 FFR.[15] Wearing an N95 FFR at low work levels for 1 hour results in mixed inhalation/exhalation N95 FFR dead space O_2 levels below (16.6%) ambient levels,[23,24] but these have not resulted in SpO_2 values <95%, because the sigmoidal shape of the oxygen-hemoglobin dissociation curve allows healthy individuals to maintain an SpO_2 value of 92%-98% breathing fractions of inspired air (FiO_2) below normal ambient level (0.21).[25] Furthermore, the rightward shift of the oxygen-hemoglobin curve during pregnancy favors unloading of O_2 in the periphery and O_2 transfer across the placenta.

$PtcCO_2$

$PtcCO_2$ declines with pregnancy to 32-34 mm Hg owing to increased minute ventilation necessitated by the added metabolic demands, ventilatory stimulant effects of elevated progesterone, and need to develop a fetal/maternal CO_2 gradient.[10] No significant differences in $PtcCO_2$ were found between the pregnant and nonpregnant subjects (Table 1). No subject was hypercapneic, and none had an increase in baseline $PtcCO_2$ >3 mm Hg (Table 2). At low work levels over 1 hour, mixed inhalation/exhalation N95 FFR deadspace CO_2 (2.8%-2.9%)[23,24] exceeds ambient levels and results in rebreathing of CO_2; however, CO_2 retention is generally minimal, because respirator deadspace CO_2 ≤2% is fully compensable in the short term.[26] These findings, along with the mild increase (ie, 7.6 mm Hg) in $PtcCO_2$ reported with 12 hours of N95 FFR use by female health care workers,[27] suggest that CO_2 retention sufficient to cause fetal distress ($PtcCO_2$ ≥60 mm Hg)[28,29] should not occur in healthy pregnant women wearing an N95 FFR. The finding of a significant effect of N95 FFR use on $PtcCO_2$ over time during exercise (P = .04) is related to the rebreathing of higher CO_2 levels generated during exercise.

Chest wall and aural temperatures

The trapping of warmed, exhaled air results in an increase in N95 FFR deadspace temperature over ambient air temperature.[30] No significant differences in T_{chest} and T_{aural}

between pregnant and non-pregnant subjects were noted (Table 1), and the minimal increases observed reflect that ~10% of body heat is normally dissipated by respiration, so that rebreathing expelled air from the N95 FFR deadspace has minimal effect on core temperature.[31] The significant effect of N95 FFR use on T_{chest} ($P < .001$) may indicate a greater effect of rebreathed warm air on the peripheral temperature of skin closest to the pulmonary system (ie, chest wall).[32]

FHR

Use of an N95 FFR was not associated with any significant effects on FHR during any of the activity phases. No fetal bradycardia or tachycardia was noted (Table 3), reflecting the lack of significant impact on the measured maternal physiological variables.

BRPE

All subjects similarly rated the sedentary portions of the study (ie, standing and sitting) as compatible with “very, very light” and the exercise portion as consistent with “very light” in terms of exertion[19] (Table 2). Wearing an N95 FFR was perceived as not significantly different between groups as relates to energy expenditure, similar to previous reports,[23,24,33] likely related to the decreased filter resistance of modern N95 FFRs[33,34] on breathing resistance.

FSPC

All subjects indicated thermal ratings ranging from “neither hot nor cold” to “slightly hot”[18] (Table 3). The greater heat perception among all subjects when wearing an N95 FFR ($P \leq .001$) is likely related to the respirator’s barrier effects on facial skin heat loss mechanisms (evaporation, convection) and increased N95 FFR dead space temperature.[31]

Limitations of this study include the relatively small number of pregnant subjects studied (n = 22), reflecting the difficulty recruiting experienced RPD users from this special population. In addition, because only 3 of our 22 pregnant subjects (13%) had a BMI >30, we cannot comment on the effects of N95 FFR use by obese pregnant women. Although few pregnant subjects were in their third trimester, no significant differences in pulmonary function tests between the second and third trimesters have been reported.[35] Only 2 N95 FFR styles (cup-shaped and flat fold) were tested, so that we cannot comment on other styles (eg, duckbill, pleated). Only healthy pregnant women were recruited for the study, so that the impact of N95 FFR use by pregnant women with significant cardiopulmonary disorders is unknown, although in patients with various mild airway diseases (eg, COPD, asthma, chronic rhinitis), N95 FFRs were found to have less physiological impact than other negative-pressure RPDs.[36]

The use of an N95 FFR by healthy, pregnant women in advanced stages of pregnancy did not result in significant differences in physiological and subjective findings compared with healthy, nonpregnant women during sedentary activities and exercise over 1 hour. These findings, and recent evidence of physiological tolerance to long-term (12 hours) use of an N95 FFR by nonpregnant women,[27] suggest that N95 FFRs are likely to be safe for use by healthy, pregnant women and should serve as a stimulus for a larger study. Research

reporting that the use of medical/surgical masks results in similar physiological effects as N95 FFR[37] implies that these protective facemasks are also safe for use during pregnancy. Pregnant women with concerns about the use of N95 FFRs should consult a licensed medical provider with knowledge of the topic.

Acknowledgments

Funded by internal operating funds of the National Personal Protective Technology Laboratory/National Institute for Occupational Safety and Health. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of product names does not imply endorsement.

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Table 1

Physiological variables for pregnant and nonpregnant subjects wearing an N95 FFR

	Trial			
	Nonpregnant subjects (n = 22)		Pregnant subjects (n = 22)	
Study variable*	No respirator	N95 FFR	No respirator	N95 FFR
Standing				
HR				
1 min	71.0 (13.4)	74.9 (14.2)	89.3 (13.8)	95.5 (13.0)
20 min	76.9 (14.8)	78.6 (22.2)	96.3 (16.7)	100.1 (14.1)
RR				
1 min	17.8 (3.5)	16.6 (3.8)	18.0 (2.34)	17.9 (3.3)
20 min	17.3 (3.6)	17.2 (3.14)	17.6 (2.9)	16.3 (1.6)
SpO_2				
1 min	98.9 (0.9)	99.1 (0.5)	99.2 (0.7)	99.0 (0.5)
20 min	98.7 (1.6)	99.1 (0.6)	99.1 (0.6)	99.0 (0.5)
$PtcCO_2$				
1 min	36.7 (3.5)	37.5 (3.5)	32.1 (1.8)	32.6 (2.4)
20 min	37.4 (4.6)	35.1 (8.4)	32.2 (2.2)	32.2 (1.5)
T_{chest}				
1 min	34.9 (1.4)	34.2 (1.9)	35.7 (0.7)	34.8 (1.4)
20 min	34.8 (1.3)	34.8 (1.3)	35.6 (0.8)	35.4 (1.0)
T_{aural}				
1 min	36.6 (0.4)	36.7 (0.4)	36.8 (0.3)	36.8 (0.3)
20 min	36.6 (0.4)	36.4 (0.4)	36.7 (0.4)	36.7 (0.3)
Exercise				
HR				
1 min	87.9 (18.9)	89.3 (18.3)	106.2 (11.8)	106.5 (13.8)
20 min	98.8 (18.2)	105.5 (15.9)	120.3 (17.1)	118.9 (14.6)
RR				
1 min	21.9 (3.3)	19.7 (3.9)	21.5 (4.3)	20.6 (3.7)
20 min	26.4 (4.2)	24.9 (6.1)	26.9 (4.2)	24.9 (4.7)
SpO_2				
1 min	98.7 (1.1)	98.6 (1.0)	98.7 (1.3)	98.9 (0.7)
20 min	98.7 (1.2)	98.8 (0.7)	98.9 (0.7)	98.7 (1.3)
$PtcCO_2$				
1 min	36.7 (6.0)	37.6 (2.9)	32.3 (2.2)	32.9 (2.36)
20 min	37.4 (3.3)	38.7 (3.1)	31.3 (3.0)	33.3 (2.2)
T_{chest}				
1 min	34.9 (1.2)	34.8 (1.3)	35.6 (0.9)	35.4 (0.9)
20 min	35.4 (1.1)	35.4 (0.9)	35.9 (0.8)	36.1 (0.8)
T_{aural}				

	Trial			
	Nonpregnant subjects (n = 22)		Pregnant subjects (n = 22)	
Study variable*	No respirator	N95 FFR	No respirator	N95 FFR
1 min	36.6 (0.4)	36.4 (0.4)	36.7 (0.4)	36.6 (0.3)
20 min	36.7 (0.4)	36.5 (0.4)	36.8 (0.4)	36.7 (0.3)
Sitting				
HR				
1 min	81.2 (16.4)	82.7 (18.3)	99.0 (15.2)	98.8 (15.0)
20 min	70.6 (12.8)	73.7 (14.8)	91.3 (12.5)	90.6 (11.0)
RR				
1 min	20.2 (3.7)	19.3 (4.7)	19.1 (4.1)	19.9 (4.12)
20 min	17.8 (3.8)	17.3 (3.2)	17.9 (3.3)	16.9 (3.7)
SpO_2				
1 min	98.8 (1.7)	98.8 (1.1)	99.1 (1.0)	99.1 (0.7)
20 min	99.0 (0.7)	99.2 (0.7)	99.2 (0.6)	99.2 (0.6)
$PtcCO_2$				
1 min	37.1 (3.2)	37.3 (4.5)	31.3 (2.4)	32.3 (2.8)
20 min	36.9 (3.0)	36.8 (3.1)	31.9 (2.6)	32.4 (2.5)
T_{chest}				
1 min	35.6 (1.0)	35.6 (1.1)	35.9 (0.9)	36.0 (0.7)
20 min	35.6 (1.1)	35.5 (1.1)	36.1 (0.9)	36.0 (0.8)
T_{aural}				
1 min	36.7 (0.4)	36.5 (0.4)	36.8 (0.3)	36.7 (0.3)
20 min	36.7 (0.4)	36.4 (0.5)	36.8 (0.3)	36.6 (0.3)

Data are mean (SD).

*None of the results comparing study variables between pregnant and nonpregnant subjects are statistically significant ($P > .05$).

Table 2

Subjective variables for pregnant and nonpregnant subjects wearing an N95 FFR

	Trial			
	Nonpregnant subjects (n = 22)		Pregnant subjects (n = 22)	
Study variable	**No respirator**	**N95 FFR**	**No respirator**	**N95 FFR**
Standing				
BRPE				
1 min	6.5 (1.1)	6.0 (1.5)	6.7 (1.4)	6.4 (0.7)
20 min	6.7 (1.2)	6.9 (1.5)	6.9 (1.4)	7.3 (1.8)
FSPC				
1 min	4.6 (0.8)	4.6 (1.0)	4.5 (0.7)	4.9 (0.4)
20 min	4.4 (0.6)	4.9 (0.8)	4.6 (0.7)	5.4 (1.0)
Exercise				
BRPE				
1 min	8.1 (1.8)	8.4 (2.1)	8.4 (1.9)	9.0 (2.0)
20 min	9.7 (2.6)	10.8 (2.2)	10.6 (2.5)	11.5 (3.1)
FSPC				
1 min	4.8 (1.0)	5.1 (0.7)	4.6 (0.5)	5.1 (0.7)
20 min	5.7 (1.0)	6.1 (1.0)	5.5 (1.0)	6.3 (1.0)
Sitting				
BRPE				
1 min	7.0 (1.6)	7.4 (1.6)	7.0 (1.6)	7.8 (2.1)
20 min	6.4 (1.1)	6.3 (0.5)	6.4 (1.1)	6.5 (0.6)
FSPC				
1 min	5.5 (1.1)	5.8 (1.0)	5.0 (0.5)	5.7 (0.9)
20 min	4.5 (0.7)	5.0 (0.9)	4.7 (0.5)	5.0 (0.7)

Data are mean (SD).

Table 3

FHR responses to sedentary activity and exercise in pregnant women (n = 17)

	Trial	
Study variable	**No respirator**	**Respirator**
Standing		
1 min	140.6 (10.7)	143.4 (8.9)
20 min	145.9 (10.6)	144.5 (10.0)
Exercise		
1 min	145.6 (7.6)	141.7 (8.5)
20 min	148.8 (11.6)	149.1 (9.5)
Sitting		
1 min	144.5 (10.7)	143.6 (12.6)
20 min	148.1 (10.5)	150.0 (12.8)

Data are mean (SD).